Efficiency in Standards Development and Revision

USP will proactively evaluate and enhance the process for developing and updating standards to maintain and continuously optimize their impact. In doing so, USP will consider the perspectives and implications of process modifications from FDA, industry, practitioners, and other stakeholders. A focus of this work will be to explore new approaches for the efficient sharing of information that is critical to standards development, along with the information needed for the evaluation of fit-for-purpose analytical methods and specifications, and the integration of appropriate scientific and manufacturing advances into USP standards.

Year 2 Update

USP standards support global medicines supply chain resilience, helping ensure access to safe, quality medicines people can trust. USP engaged with FDA, industry, healthcare practitioners, and other stakeholders to maintain a modernized USP-NF compendia through collaboration and implementation of efficient processes for continually developing and revising quality standards. This included working with FDA and industry on new approaches for sharing the information needed for efficient standards setting, advancing access to quality medicines, and helping protect patients.

Key areas of progress over the past fiscal year include:

Adapt-Transform-Progress – Over the past several years, USP has continued to implement solutions, including its Adapt-Transform-Progress (ATP) initiative, to increase the efficiency and effectiveness of the standards-development process and systems. Under ATP, multiple pilots for case-based staffing processes were implemented as the necessary foundational information was captured and applied. In addition, multiple software releases within the USP Business Process Management (BPM) application were deployed to support Reference Standards development. The discovery phase for the BPM application for documentary standards was also completed ahead of the initial release (known as “Minimum Viable Product 1”) in fall 2022.

Standards Engagement Model – This cycle, USP is focused on advancing a more iterative and agile approach to standards development. This approach stimulates early discussion, allowing for more rapid development of standards, further ensuring the availability of quality-assured medicines based on engaging the right volunteers and stakeholders at the right time. During the year, this approach included exploration of health equity principles as a key
consideration for standards-setting activities and broadened efforts at inclusivity among independent volunteer experts through expansion of USP’s Call for Candidates and the Scientific Expert Fellowship program. USP also continued to analyze and streamline approaches for direct stakeholder engagement in support of the Standards Engagement Model and Science Quality Framework (see below). To accomplish this, USP deployed new stakeholder engagement tools including open forums, round tables, webinars, and workshops, which have drawn 7,400+ stakeholders to events targeted at specific standards-setting areas and challenges. The majority of stakeholder registrations in Fiscal Year 2022 were for events focusing on revisions to *USP* General Chapters <795> and <797> on compounding, how USP handles public comments on proposed revisions to the *USP-NF* that are published in the *Pharmacopeial Forum*, and the USP Biologics Stakeholder Forum on analytical solutions to support advanced biomanufacturing.

**Science Quality Framework** – This framework establishes a consistent set of focus areas and principles that help guide our science priorities and the work of our expert bodies. Specific accomplishments included the introduction of new standards, revisions, and other deliverables with a focus on complex generic drugs, pharmaceutical continuous manufacturing, and improvement of performance testing for dissolution.

**Government Liaison Program** – USP increased the total number of FDA government liaisons that serve across USP’s expert bodies to 249, further expanding involvement of this priority stakeholder in our standards-setting activities. As part of our commitment to continuous improvement, we also proposed a real-time reporting mechanism to be utilized by FDA government liaisons to allow us to pinpoint issues and identify trends across expert bodies more rapidly. The proposal was approved by all FDA centers and is slated to launch by fall 2022.

**Information Sharing** – USP and FDA continued to collaborate on efforts to increase critical information exchange between USP, industry, and FDA for standards development, including the revision of compendial processes. USP and FDA continue to discuss the incorporation of language into FDA communications with industry during the application filing process, with the goal of educating industry about how to work with USP to develop standards.

**Planned for Year 3**

- USP will implement a BPM application for documentary standards, continue to pursue further development of BPM applications to support standards creation, and review and implement further case-based standards-development approaches.
- USP will continue to evaluate opportunities to engage USP volunteers and other stakeholders in new and more targeted ways, including through learnings from virtual engagements.
- By fall 2022, USP will launch a real-time mechanism for FDA government liaisons to report operational challenges and successes, allowing USP to identify trends and pinpoint issues across expert bodies more rapidly.
- USP will conduct a joint webinar on standards development with FDA and the Association for Accessible Medicines in the summer of 2023.
USP will work with FDA to develop a memorandum of understanding to facilitate the timely sharing of information to support the efficient development of quality standards and build upon collaborative efforts.

**Contact**
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